In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 15-369V

(not to be published)

CARMEN MORENO LOZANO,	*	
	*	
Petitioner,	*	Filed: August 4, 2017
	*	
v.	*	Ruling on Entitlement; Tetanus Diphtheria-acellular-pertussis ("Tdap") Vaccine; Acute Disseminated Encephalomyelitis ("ADEM").
	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
	*	
Respondent.	*	
	*	

Christina Ciampolillo, Conway Homer, P.C., Boston, MA, for Petitioner.

Robert Coleman, U.S. Dep't of Justice, Washington, DC, for Respondent.

RULING ON ENTITLEMENT[1]

On April 13, 2015, Mrs. Carmen Lozano filed this action seeking compensation under the National Vaccine Injury Compensation Program (the "Vaccine Program"),[2] alleging that she developed acute disseminated encephalomyelitis ("ADEM") due to receipt of the tetanus-diphtheria-acellular-pertussis ("Tdap") vaccine on July 15, 2012. Petition ("Pet.") (ECF No. 1) at 1. An entitlement hearing in the matter was held on June 14, 2017. After considering the record as a whole, and for the reasons explained below, I find that Petitioner has carried her burden establishing causation, and therefore has demonstrated entitlement to compensation under the Vaccine Program.

[1] Although this Ruling has been formally designated "not to be published," it will nevertheless be posted on the Court of Federal Claims's website in accordance with the E-Government Act of 2002, 44 U.S.C. § 3501 (2012). **This means the ruling will be available to anyone with access to the internet**. As provided by 42 U.S.C. § 300aa-12(d)(4)(B), however, the parties may object to the decision's inclusion of certain kinds of confidential information. Specifically, under Vaccine Rule 18(b), each party has fourteen days within which to request redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, the Ruling in its present form will be available. *Id.*

[2] The Vaccine Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3758, codified as amended at 42 U.S.C. §§ 300aa-10 through 34 (2012) ("Vaccine Act" or "the Act"). Individual section references hereafter will be to § 300aa of the Act (but will omit that statutory prefix).

I. Factual Background

Petitioner's medical history prior to vaccination shows that she was largely healthy. She was, however, pregnant just before she received the vaccine at issue. During (and even prior to) her pregnancy, Mrs. Lozano experienced some symptoms that have been identified by Respondent as relevant to the case. Thus, Petitioner reported some bilateral numbness in her fingers and arms in the second half of her pregnancy, around February 2012. Ex. 6 at 3. Her family also reported that prior to her pregnancy, Mrs. Lozano had experienced an episode of eye drooping, and had on one occasion found it difficult to open a jar. *Id*. These prior incidences are not addressed in contemporaneous medical records, but were later mentioned at a neurological visit in September 2012, about two months after vaccination. *See generally*, Ex. 6.

On July 14, 2012, Mrs. Lozano gave birth to a baby girl at Community Memorial Hospital ("CMH") in Ventura, California. Ex. 4 at 151. The next day, while still hospitalized, Petitioner received the Tdap vaccine. Ex. 1 at 1. Two weeks later, on July 30, 2012, Petitioner reported to Ventura County Obstetrics and Gynecology ("VCOG") complaining of a low grade fever, body aches, and breast tenderness, which she informed treaters had persisted since leaving the hospital. Ex. 3 at 2. The nurse practitioner she saw at this visit suspected that Mrs. Lozano had early mastitis,[3] and prescribed medication, while encouraging Petitioner to continue to breast feed. *Id*. Petitioner thereafter continued to experience the same persistent symptoms, in addition to fatigue. *Id*.

On August 9, 2012 (25 days after vaccination), Mrs. Lozano went to the emergency department at CMH complaining of abdominal pain and difficulty urinating. Ex. 4 at 128-9. Lab work performed at this time showed no signs of infection, so Petitioner's treaters concluded that her symptoms were likely related to her mastitis and discharged her. *Id.* at 130. However, Mrs. Lozano's symptoms continued to worsen, and she therefore returned to the CMH later that day, now reporting increased weakness so severe that she required a family member to inform treaters of her symptoms. *Id.* at 202-6. At this point, Petitioner's symptoms (in addition to what she had previously listed) included fever, weakness, feeling off balance, vision changes, neck pain, headache, vomiting, and feeling dizzy. *Id.* A brain MRI was performed and showed "numerous focal and patchy high signal intensity lesions involving the brainstem, cerebellopontine angles, right cerebellum, basal ganglia, corpus callosum and subcortical white matter," which suggested to the radiologist that Petitioner possibly had multiple sclerosis ("MS"), ADEM, or vasculitis. *Id.* at 82.

[3] Mastitis is the inflammation of the breast. *Dorland's Illustrated Medical Dictionary* 1111 (32 ed. 2003) (hereinafter "*Dorland's*").

Due to the severity of her symptoms, Mrs. Lozano was admitted to CMH for further evaluation, including a consultation with neurologist Dr. Francisco Torres. Ex. 4 at 49. After review of Mrs. Lozano's symptoms, her lab reports, and her imaging, Dr. Torres opined that Petitioner had possibly experienced an attack of MS that should be treated with Solu-Medrol[4] while Petitioner awaited a more comprehensive workup as well as physical therapy for her ambulatory problems. *Id.* at 45-6.

On August 13, 2012, Mrs. Lozano was discharged after it was determined that the steroid treatment was helping with her symptoms. Ex. 4 at 7-9. Her working diagnosis at discharge was MS, but certain evidence that would corroborate the diagnosis was absent: Petitioner's lumbar puncture had established that she was negative for oligoclonal bands[5] (the presence of which are associated with MS), and the results of tests that would reveal the levels of her myelin basic protein antibodies were still pending. *Id*. Petitioner was instructed to follow up with Dr. Timothy Sheehy, and she did so on August 17, 2012. *Id*.

Dr. Sheehy thought a second opinion was necessary to insure that Petitioner's diagnosis was fitting given all of her symptoms and test results. Ex. 5 at 19. Before Mrs. Lozano could seek that second opinion, however, she returned to the CMH emergency department on August 27, 2012. She now presented with burning in her chest, slurring of words, hearing changes, and numbness in her tongue. Ex. 4 at 24-31. Petitioner was discharged later that day with a diagnosis of an MS flare, but was instructed to see her primary care physician and undergo a second MRI of the spine. *Id*. That MRI was performed the next day and showed "[p]atchy areas of altered signal intensity within the thoracic spinal cord…worrisome for foci of demyelination." Ex. 5 at 20.

On September 9, 2012, Mrs. Lozano sought a second opinion from Dr. Barbara Giesser, a neurologist at the University of California Los Angeles Neurology Outpatient Clinic. Dr. Giesser provided a detailed medical history of Petitioner since first manifestation of her symptoms in late July 2012, and recorded that Mrs. Lozano's current symptoms included;

> "numbness bilaterally from her chest down to her lower torso, left arm numbness and paresthesias, right arm weakness and paresthesias, right leg weakness, and burning

[4] Solu-Medrol is the trademark for a preparation of methylprednisolone sodium succinate, a medication used in emergency situations to increase a patient's blood level of methylprednisolone. *Dorland's* 1731, 1154. Solu-Medrol can be used to treat a myriad of illness, including arthritis and Guillain-Barré syndrome, as it is anti-inflammatory and relieves pain as well. *Auch v. Sec'y of Health & Human Servs.*, No. 12-673V, 2017 WL 1034396, at *2 (Fed. Cl. Spec. Mstr. Jan. 13, 2017); *Carrino v. Sec'y of Health & Human Servs.*, No. 08-0266V, 2013 WL 3328903, at *9 (Fed. Cl. Spec. Mstr. June 6, 2013).

[5] Oligoclonal bands are discrete bands of immunoglobulins with decreased electrophoretic mobility; their appearance in electrophoretograms of cerebrospinal fluid when absent in the serum is a sign of possible multiple sclerosis or other diseases of the central nervous system. *Dorland's* at 197.

> around her left waist. She states that her cognition has declined and that she is thinking slower and forgetting objects, and having short term memory issues."

Ex. 6 at 3-6. Dr. Giesser's differential diagnosis included post-viral encephalitis/myelitis, with a working diagnosis of "Clinically Isolated Syndrome" (a condition similar to MS), and she prescribed several medications to help improve her ongoing symptoms. *Id.*

Throughout the fall of 2012, Mrs. Lozano continued to see Dr. Sheehy, noting that she was still experiencing the burning sensation from her back to chest with decreased memory, cognition, and depression. Ex. 5 at 13-15. On February 13, 2013, however, a repeat MRI was performed, and it showed dramatic improvement, suggesting that ADEM was a more likely etiology, which was confirmed through later serological findings. Ex. 5 at 7.

Since the winter of 2013, Petitioner's doctors have continued to opine that ADEM is the most likely explanation for Petitioner's symptoms, which she continues to seek treatment for, given that she has persistent lingering neurological and physical impairments that keep her on disability, despite normal MRI results. No medical records were filed in this case suggesting that any treater doubted, based on the overall medical history, that ADEM was the proper diagnosis, and Mrs. Lozano has experienced no second set of neurologic symptoms that could reflect a flare-up of symptoms that might instead suggest that MS was actually the explanation for her condition.

II. Expert Opinions and Testimony

The parties both offered expert neurologists to opine on the merits of this case. Each expert provided an expert report and testified at the hearing.

A. Dr. Norman Latov

Petitioner's expert, Norman Latov, M.D., Ph.D, submitted two expert reports in this case and also testified at the hearing. *See e.g.*, Ex. 21, dated Nov. 16, 2015 ("Latov Ex. Rep."); Ex. 23, dated June 13, 2016 ("Latov Supp. Rep."); Transcript ("Tr.") at 4-52, 103-6.

Dr. Latov attended the University of Pennsylvania to complete his medical and doctorate degree. Tr. at 5; *see also* Ex. 22, dated Nov. 16, 2015. He completed his residency in neurology and immunology at Columbia University before joining their faculty. Tr. at 5. Dr. Latov is now on the faculty at Weill Cornell Medicine, where he directs a peripheral neuropathy center as well as serving as a professor of neurology and neuroscience, and being an attending neurologist. *Id.* He has previously conducted research in the area of autoimmune neurological diseases. *Id.* at 6. Dr. Latov estimates that currently about 30 percent of his time is spent seeing patients, while the rest is dedicated to administrative tasks, teaching, and research. *Id.* In his clinical practice he commonly treats patients with peripheral neuropathies such as Guillain-Barré syndrome ("GBS"), chronic inflammatory demyelinating polyneuropathy (CIDP), MS, and transverse myelitis. *Id.* at 7. Due to

the uncommonness of ADEM, Dr. Latov only has had occasional experience in treating the condition p (about one such patient every one to two years) as a part of his duties as an attending physician. *Id.* at 8.

Dr. Latov opined that Mrs. Lozano's ADEM was the product of her receipt of the Tdap vaccine. Tr. at 8. He began by describing ADEM as an autoimmune demyelinating disease of the central nervous system that attacks the white matter of the brain and spinal cord of its patients. Latov Ex. Rep. at 5. Dr. Latov added that ADEM is known to be triggered most commonly by infection or vaccination. Tr. at 10. He noted that ADEM can be confirmed through lesions on an MRI, inflammatory changes in the spinal fluid, and a corresponding lack of oligoclonal bands (the presence of which would reflect ongoing inflammation originating in the CNS rather than coming from outside it). *Id*. Javed, A., Chapter 35 - Acute disseminated encephalomyelitis. In C. T. a. J. B. Alex (Ed.), Handbook of Clinical Neurology, 123 (2014), at 709, 711, filed as Ex. 21, Tab F. In keeping with its acute nature, Dr. Latov noted, a hallmark of ADEM is its subsequent resolution – something that can be confirmed by later MRIs. *Id*.

Dr. Latov cited several pieces of medical literature that have observed an association between tetanus-containing vaccines akin to what Mrs. Lozano received and ADEM. *See, e.g.*, W. Huynh, *et. al*, *Post-vaccination encephalomyelitis: literature review and illustrative case*, J. Clinical Neuroscience, 15(12) at 1315-22 (2008), filed as Ex. 21, Tab E ("Huynh"); D. Karussis D. and P. Petrou, *The spectrum of post-vaccination inflammatory CNS demyelinating syndromes,* Autoimmunity Rev. 13(3) at 215-24 (2014), filed as Ex. 21, Tab G ("Karussis"). The Huynh authors performed a medical literature review of studies regarding post-vaccination and post-infectious ADEM. Huynh at 1315. Huynh found that ADEM was associated with several vaccines, including diphtheria-tetanus-polio. *Id*. at 1316.

Karussis also observes an association between tetanus-containing vaccines and ADEM. Karussis at 216. Moreover, Karussis considered the prevailing hypothesis of molecular mimicry as a mechanistic explanation for ADEM's pathogenesis, describing it as occurring when an "antigen of viral origin cross-react[s] with myelin components (molecular mimicry) and in a secondary manner induce a hyperergic reaction, that leads to the development of disseminated demyelination." *Id*. at 217. Dr. Latov also proposed bystander activation as an alternative mechanism, by which components of a vaccine might precipitate or exacerbate an autoimmune reaction from immune cells not specifically responding directly to the vaccine's antigens, and cited literature to support the concept.[6]

[6] Bystander activation occurs when immune system cells that were previously suppressed, or anergic, are broken down by an existing/ongoing immune response to infection (or an autoimmune response to vaccination), causing immune tolerance created by those cells to similarly be destroyed and thereby allowing the dysregulation of the immune response to continue or expand. Latov Ex. Rep. at 5. In support, Dr. Latov presented two animal studies involving the induction of "experimental autoimmune encephalomyelitis," or EAE, which provides a model of ADEM. *Id.*

Dr. Latov next connected his theory to the medical record, in an effort to show it working out in Mrs. Lozano's circumstances. First, he proposed the Tdap vaccine acted as the trigger initiating Petitioner's autoimmune response. Tr. at 9. He also recognized that Petitioner had the proper post-vaccination signs, such as trustworthy neurological findings indicating multiple sites of involvement, the presence of demyelinating lesions on her MRIs, an increased number of white blood cells in her CSF fluid, and the absence of oligoclonal bands from the same testing (since their presence would be more likely associated with MS). *Id*. Finally, and most significantly to Dr. Latov, the lesions observed on Mrs. Lozano's first MRIs resolved months later, and she has since experienced no additional demyelinating events. *Id*.

Dr. Latov was asked to reconcile the inclusion of MS in Petitioner's initial differential diagnosis with her treaters' later conclusion (which he accepted) that the proper diagnosis was ADEM. To do so, he pointed to the same test results and evidence of resolved lesions discussed above. Tr. at 9-10. He also noted that as Mrs. Lozano's physicians evaluated her condition over time, they acknowledged the need to seek out a variety of treater views in understanding the nature of her illness, thereby increasing his confidence in their ultimate conclusion, as it was the product of thorough medical care. *Id*. at 50. Petitioner's treaters eventually changed their diagnosis to ADEM after Mrs. Lozano's MRIs cleared and she had experienced no subsequent neurological episodes. *Id.* at 10. He accepted the decisions of her initial treaters to employ medications and treatments used for MS as the safer course, given that MS can worsen significantly if not treated quickly, but noted that such treatments were subsequently abandoned successfully once the clinical evidence better supported the ADEM diagnosis. *Id*. at 42, 44.

In addition to questions about Mrs. Lozano's diagnosis, Dr. Latov also addressed some of the purported pre-vaccination neurologic symptoms from Petitioner's pregnancy or before, such as her hand numbness. Latov Ex. Rep. at 6. Dr. Latov rejected the idea that hand numbness was related to Petitioner's ADEM, and instead proposed that it as likely reflected carpal tunnel syndrome caused by increased tissue swelling common in the latter parts of pregnancy. Tr. at 34. He did concede however, that any undiscovered and preexisting brain lesions that had developed prior to vaccination would have appeared the same in the MRI that Mrs. Lozano had shortly after the onset of her symptoms. *Id*. at 30-31. Dr. Latov further stated that it would be impossible to know when any of the lesions actually began without prior MRIs. *Id*. at 31. He nevertheless opined that if the numbness in Mrs. Lozano's hand was caused by a spinal lesion, he would have expected Mrs. Lozano to have also experienced symptoms in her legs and altered reflex responses, which she did not report in her numerous doctors' visits during the latter part of her pregnancy. *Id*. at 34-35.

Researchers have been able to induce EAE by injecting a ganglioside that would target cells that were normally dormant, thus exhibiting bystander activation as a casual mechanism. *Id.*

Dr. Latov further contested the meaningfulness of other purported instances of neurologic symptoms, such as Petitioner's family's report that she once had found it difficult to open a jar, or her late 2011 eye droop. Tr. at 36. He opined that if both of these incidences had been related to a neurological condition, he would have expected other symptoms to have also been present and recorded in the medical record. *Id*. For example, if the eye droop had been a neurological condition, Dr. Latov opined that Petitioner would have experienced worsening drooping over time - yet there was no evidence in the medical records that the condition persisted or was reported by Petitioner. *Id*.

Finally, Dr. Latov disputed Respondent's contention that Mrs. Lozano actually was suffering from posterior reversible encephalopathy syndrome ("PRES") rather than ADEM. Tr. at 47. As Dr. Latov described, PRES is a condition marked by the presence of edema in the posterior part of the brain as revealed on MRIs, and agreed that it was not unreasonable to propose it for someone experiencing symptoms post-partum, as was the case with Mrs. Lozano. *Id*. at 48. The majority of patients suffering from PRES present with a decreased level of consciousness and have seizures. *Id*. But here, Dr. Latov maintained, those symptoms were not present in Mrs. Lozano. More importantly, her MRIs showed lesions throughout the spinal cord and brain —not just in the posterior region – and detected no edema, nor had she experienced seizures or decreased consciousness. *Id*. at 47. In addition, the symptoms that led Mrs. Lozano to go to the ER occurred almost four weeks after she gave birth—whereas in PRES, symptoms would more commonly arise no more than a few days after giving birth (given the relationship of PRES to a retained placenta).[7] *Id*. at 48. In addition, none of Petitioner's treaters ever concluded that PRES was a reasonable explanation for her condition. *Id.* at 47. Dr. Latov thus concluded that PRES was an improper diagnosis given Petitioner's clinical presentation. *Id*. at 48-49.

B. Dr. Thomas Leist

Respondent's expert, Thomas Leist, M.D., Ph.D, submitted one expert report in this case and testified at the hearing. *See e.g.*, Resp't's Ex. A, dated Mar. 29, 2016 ("Leist Ex. Rep."); Tr. at 53-95, 102.

Dr. Leist attended the University of Zurich, where he obtained his Ph.D. in immunology and biochemistry as well as a post-doctorate degree in experimental pathologies. Tr. at 53; *see*

[7] A placenta not removed within 30-60 minutes after delivery is known as a retained placenta; if left untreated, a retained placenta can cause a severe infection or blood loss to the mother. *Pregnancy week by week: Placenta: How it works, what's normal*, Mayo Clinic (Mar. 13, 2015), http://www.mayoclinic.org/healthy-lifestyle/pregnancy-week-by-week/in-depth/placenta/art-20044425 (last accessed July 21, 2017). In the context of PRES, a retained placenta is often to blame for the toxemia following birth, often causing eclampsia (increased blood pressure), which can ultimately result in PRES. Bartynski. *Posterior Reversible Encephalopathy Syndrome, Part 1: Fundamental Imaging and Clinical Features,* Am. J. Neuroradiol 29:1036-42 (2008).

also, Ex. B, dated Mar. 29, 2016. He also completed a post-doctorate at the University of California, Los Angeles and attended medical school in the United States at the University of Miami. *Id.* He then completed a residency in neurology at Cornell University before becoming a fellow at the National Institute of Health. Tr. at 54. Dr. Leist is board certified in neurology and currently serves as a professor of neurology at Thomas Jefferson University in Philadelphia, Pennsylvania as well as directing the MS center and guiding the MS or the neuro-immunology fellowship program. *Id*. at 53. As a part of this role, he sees about 2,700 patients diagnosed with MS (whether solely or as part of a differential diagnosis), as well as seeing patients in tertiary care hospitals affiliated with Thomas Jefferson University Hospital. *Id.* at 57.

Dr. Leist opined that Mrs. Lozano actually had PRES, and that it was not caused by the Tdap vaccine she received in July 2012. Leist Ex. Rep. at 9. He based this conclusion on Mrs. Lozano's rapid onset of neurological symptoms after giving birth—rather than following vaccination— stressing that PRES is a known vascular complication following pregnancy, especially with late onset preeclampsia. *Id*. at 9-10. Although Mrs. Lozano was not formally diagnosed with preeclampsia during her pregnancy, she exhibited elevated blood pressure during the first week of August 2012 (or about two weeks after she gave birth), and shortly before the onset of her neurological symptoms. *Id*. at 9. But in his view, a mother's blood pressure should be lower in the post-partum phase, thereby corroborating the possibility that she was experiencing a vascular-related condition. Tr. at 69.

In response to the fact that PRES was never considered for Petitioner by any of her treating physicians, Dr. Leist pointed to Petitioner's initial MRI from August 2012. The radiologist who performed the MRI included vasculopathy (a broad category that would include PRES) in the differential diagnosis. Tr. at 62. Moreover, he proposed, if Mrs. Lozano's condition were demyelinating he would have expected to see evidence of the lesions in subsequent brain MRIs given Mrs. Lozano's ongoing neurological sequelae. *Id.* at 63. Instead, the lesions had completely resolved, leading Dr. Leist to prefer PRES as the diagnosis congruent with Mrs. Lozano's clinical picture. *Id*. Dr. Leist admitted that outside of the radiologist's statement, none of Petitioner's physicians ever subsequently considered PRES or vasculitis as the proper diagnosis, but he opined that this was because her physicians had not given sufficient weight to the fact that she was post-partum at the time of her presenting symptoms. *Id*. at 99.

III. Procedural History

As noted above, this case was filed on April 13, 2015. Within three months, the majority of medical records had been filed, along with a statement of completion and Respondent's Rule 4(c) Report. Over the next year, both parties filed expert reports and medical literature, along with a few pieces of outstanding medical records. During this time, Petitioner attempted to engage Respondent in settlement discussions by making a demand, but these efforts were unsuccessful.

I accordingly set this matter down for a hearing on June 24, 2017. Order, dated June 29, 2016 (ECF No. 27). The briefing and hearing occurred as scheduled, and this case is now ripe for a decision.

IV. Applicable Legal Standards

A. Petitioner's Overall Burden in Vaccine Program Cases

To receive compensation in the Vaccine Program, a petitioner must prove either: (1) that he suffered a "Table Injury" – *i.e.*, an injury falling within the Vaccine Injury Table – corresponding to one of the vaccinations in question within a statutorily prescribed period of time or, in the alternative, (2) that his illnesses were actually caused by a vaccine (a "Non-Table Injury"). *See* Sections 13(a)(1)(A), 11(c)(1), and 14(a), as amended by 42 C.F.R. § 100.3; § 11(c)(1)(C)(ii)(I); *see also Moberly v. Sec'y of Health & Human Servs.*, 592 F.3d 1315, 1321 (Fed. Cir. 2010); *Capizzano v. Sec'y of Health & Human Servs.*, 440 F.3d 1317, 1320 (Fed. Cir. 2006).[8] In this case, Petitioner does not assert a Table claim.

For both Table and Non-Table claims, Vaccine Program petitioners bear a "preponderance of the evidence" burden of proof. Section 13(1)(a). That is, a petitioner must offer evidence that leads the "trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the judge of the fact's existence." *Moberly*, 592 F.3d at 1322 n.2; *see also Snowbank Enter. v. United States*, 6 Cl. Ct. 476, 486 (1984) (mere conjecture or speculation is insufficient under a preponderance standard). Proof of medical certainty is not required. *Bunting v. Sec'y of Health & Human Servs.*, 931 F.2d 867, 873 (Fed. Cir. 1991). In particular, a petitioner must demonstrate that the vaccine was "not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury." *Moberly*, 592 F.3d at 1321 (quoting *Shyface v. Sec'y of Health & Human Servs.*, 165 F.3d 1344, 1352-53 (Fed. Cir. 1999)); *Pafford v. Sec'y of Health & Human Servs*., 451 F.3d 1352, 1355 (Fed. Cir. 2006). A petitioner may not receive a Vaccine Program award based solely on his assertions; rather, the petition must be supported by either medical records or by the opinion of a competent physician. Section 13(a)(1).

In attempting to establish entitlement to a Vaccine Program award of compensation for a Non-Table claim, a petitioner must satisfy all three of the elements established by the Federal

[8] Decisions of special masters (some of which I reference in this ruling) constitute persuasive but not binding authority. *Hanlon v. Sec'y of Health & Human Servs.*, 40 Fed. Cl. 625, 630 (1998). By contrast, Federal Circuit rulings concerning legal issues are binding on special masters. *Guillory v. Sec'y of Health & Human Servs.*, 59 Fed. Cl. 121, 124 (2003), *aff'd* 104 F. App'x 712 (Fed. Cir. 2004); *see also Spooner v. Sec'y of Health & Human Servs.*, No. 13-159V, 2014 WL 504728, at *7 n.12 (Fed. Cl. Spec. Mstr. Jan. 16, 2014).

Circuit in *Althen v. Sec'y of Health & Human Servs.,* 418 F.3d 1274 (Fed. Cir. 2005): "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of proximate temporal relationship between vaccination and injury." *Althen,* 418 F.3d at 1278.

Each of the *Althen* prongs requires a different showing. Under *Althen* prong one, petitioners must provide a "reputable medical theory," demonstrating that the vaccine received *can cause* the type of injury alleged. *Pafford,* 451 F.3d at 1355-56 (citations omitted). To satisfy this prong, a petitioner's theory must be based on a "sound and reliable medical or scientific explanation." *Knudsen v. Sec'y of Health & Human Servs.*, 35 F.3d 543, 548 (Fed. Cir. 1994). Such a theory must only be "legally probable, not medically or scientifically certain." *Id.* at 549.

Petitioners may satisfy the first *Althen* prong without resort to medical literature, epidemiological studies, demonstration of a specific mechanism, or a generally accepted medical theory. *Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1378-79 (Fed. Cir. 2009) (citing *Capizzano*, 440 F.3d at 1325-26). Special masters, despite their expertise, are not empowered by statute to conclusively resolve what are essentially thorny scientific and medical questions, and thus scientific evidence offered to establish *Althen* prong one is viewed "not through the lens of the laboratorian, but instead from the vantage point of the Vaccine Act's preponderant evidence standard." *Id.* at 1380. Accordingly, special masters must take care not to increase the burden placed on petitioners in offering a scientific theory linking vaccine to injury. *Contreras v. Sec'y of Health & Human Servs.*, 121 Fed. Cl. 230, 245 (2015) ("[p]lausibility . . . in many cases *may* be enough to satisfy *Althen* prong one" (emphasis in original)), *vacated on other grounds*, 844 F.3d 1363 (Fed. Cir. 2017). But this does not negate or reduce a petitioner's ultimate burden to establish his overall entitlement to damages by preponderant evidence. *W.C. v. Sec'y of Health & Human Servs.*, 704 F.3d 1352, 1356 (Fed. Cir. 2013) (citations omitted).[9]

The second *Althen* prong requires proof of a logical sequence of cause and effect, usually supported by facts derived from a petitioner's medical records. *Althen*, 418 F.3d at 1278; *Andreu*, 569 F.3d at 1375-77; *Capizzano*, 440 F.3d at 1326; *Grant v. Sec'y of Health & Human Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). In establishing that a vaccine "did cause" injury, the opinions and views of the injured party's treating physicians are entitled to some weight. *Andreu*, 569 F.3d at 1367; *Capizzano*, 440 F.3d at 1326 ("medical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether a

[9] Although decisions like *Contreras* suggest that the burden of proof required to satisfy the first *Althen* prong is less than the other two, there is ample contrary authority for the more straightforward proposition that the first *Althen* prong (as a component of the overall test) simply requires application of a preponderance evidentiary standard when evaluating if a reliable and plausible causation theory has been established. *Broekelschen v. Sec'y of Health & Human Servs.*, 618 F.3d 1339, 1350 (Fed. Cir. 2010).

'logical sequence of cause and effect show[s] that the vaccination was the reason for the injury'") (quoting *Althen*, 418 F.3d at 1280). Medical records are generally viewed as particularly trustworthy evidence, since they are created contemporaneously with the treatment of the patient. *Cucuras v. Sec'y of Health & Human Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

However, medical records and/or statements of a treating physician's views do not *per se* bind the special master to adopt the conclusions of such an individual, even if they must be considered and carefully evaluated. Section 13(b)(1) (providing that "[a]ny such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court"); *Snyder v. Sec'y of Health & Human Servs*., 88 Fed. Cl. 706, 746 n.67 (2009) ("there is nothing . . . that mandates that the testimony of a treating physician is sacrosanct – that it must be accepted in its entirety and cannot be rebutted"). As with expert testimony offered to establish a theory of causation, the opinions or diagnoses of treating physicians are only as trustworthy as the reasonableness of their suppositions or bases. The views of treating physicians should also be weighed against other, contrary evidence also present in the record – including conflicting opinions among such individuals. *Hibbard v. Sec'y of Health & Human Servs.*, 100 Fed. Cl. 742, 749 (2011) (not arbitrary or capricious for special master to weigh competing treating physicians' conclusions against each other), *aff'd*, 698 F.3d 1355 (Fed. Cir. 2012); *Caves v. Sec'y of Dept. of Health & Human Servs.*, No. 06-522V, 2011 WL 1935813, at *17 (Fed. Cl. Spec. Mstr. Apr. 29, 2011), *mot. for review den'd*, 100 Fed. Cl. 344, 356 (2011), *aff'd without opinion*, 475 Fed. App'x 765 (Fed. Cir. 2012).

The third *Althen* prong requires establishing a "proximate temporal relationship" between the vaccination and the injury alleged. *Althen*, 418 F.3d at 1281. That term has been equated to the phrase "medically-acceptable temporal relationship." *Id.* A petitioner must offer "preponderant proof that the onset of symptoms occurred within a timeframe which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation." *de Bazan v. Sec'y of Health & Human Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008). The explanation for what is a medically acceptable timeframe must also coincide with the theory of how the relevant vaccine can cause an injury (*Althen* prong one's requirement). *Id.* at 1352; *Shapiro v. Sec'y of Health & Human Servs.*, 101 Fed. Cl. 532, 542 (2011), *recons. den'd after remand*, 105 Fed. Cl. 353 (2012), *aff'd mem.*, 2013 WL 1896173 (Fed. Cir. 2013); *Koehn v. Sec'y of Health & Human Servs.*, No. 11-355V, 2013 WL 3214877 (Fed. Cl. Spec. Mstr. May 30, 2013), *mot. for review den'd* (Fed. Cl. Dec. 3, 2013), *aff'd*, 773 F.3d 1239 (Fed. Cir. 2014).

B. Law Governing Analysis of Fact Evidence

The process for making determinations in Vaccine Program cases regarding factual issues begins with consideration of the medical records. Section 11(c)(2). The special master is required to consider "all [] relevant medical and scientific evidence contained in the record," including "any diagnosis, conclusion, medical judgment, or autopsy or coroner's report which is contained in the record regarding the nature, causation, and aggravation of the petitioner's illness, disability, injury, condition, or death," as well as the "results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions." Section 13(b)(1)(A). The special master is then required to weigh the evidence presented, including contemporaneous medical records and testimony. *See Burns v. Sec'y of Health & Human Servs*., 3 F.3d 415, 417 (Fed. Cir. 1993) (it is within the special master's discretion to determine whether to afford greater weight to contemporaneous medical records than to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is evidenced by a rational determination).

Medical records that are created contemporaneously with the events they describe are presumed to be accurate and "complete" (i.e., presenting all relevant information on a patient's health problems). *Cucuras*, 993 F.2d at 1528; *Doe/70 v. Sec'y of Health & Human Servs.*, 95 Fed. Cl. 598, 608 (2010) ("[g]iven the inconsistencies between petitioner's testimony and his contemporaneous medical records, the special master's decision to rely on petitioner's medical records was rational and consistent with applicable law"), *aff'd*, *Rickett v. Sec'y of Health & Human Servs*., 468 F. App'x 952 (Fed. Cir. 2011) (non-precedential opinion). This presumption is based on the linked propositions that (i) sick people visit medical professionals; (ii) sick people honestly report their health problems to those professionals; and (iii) medical professionals record what they are told or observe when examining their patients in as accurate a manner as possible, so that they are aware of enough relevant facts to make appropriate treatment decisions. *Sanchez v. Sec'y of Health & Human Servs.*, No. 11-685V, 2013 WL 1880825, at *2 (Fed. Cl. Spec. Mstr. Apr. 10, 2013); *Cucuras v. Sec'y of Health & Human Servs.*, 26 Cl. Ct. 537, 543 (1992), *aff'd*, 993 F.2d at 1525 (Fed. Cir. 1993) ("[i]t strains reason to conclude that petitioners would fail to accurately report the onset of their daughter's symptoms.").

Accordingly, if the medical records are clear, consistent, and complete, then they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Human Servs*., No. 03-1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). Indeed, contemporaneous medical records are generally found to be deserving of greater evidentiary weight than oral testimony – especially where such testimony conflicts with the record evidence. *Cucuras*, 993 F.2d at 1528; *see also Murphy v. Sec'y of Health & Human Servs*., 23 Cl. Ct. 726, 733 (1991), *aff'd per curiam*,

968 F.2d 1226 (Fed. Cir. 1992), *cert. den'd, Murphy v. Sullivan*, 506 U.S. 974 (1992) (citing *United States v. United States Gypsum Co.*, 333 U.S. 364, 396 (1947) ("[i]t has generally been held that oral testimony which is in conflict with contemporaneous documents is entitled to little evidentiary weight.")).

However, there are situations in which compelling oral testimony may be more persuasive than written records, such as where records are deemed to be incomplete or inaccurate. *Campbell v. Sec'y of Health & Human Servs*., 69 Fed. Cl. 775, 779 (2006) ("like any norm based upon common sense and experience, this rule should not be treated as an absolute and must yield where the factual predicates for its application are weak or lacking"); *Lowrie*, 2005 WL 6117475, at *19 ("[w]ritten records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent") (quoting *Murphy*, 23 Cl. Ct. at 733)). Ultimately, a determination regarding a witness's credibility is needed when determining the weight that such testimony should be afforded. *Andreu*, 569 F.3d at 1379; *Bradley v. Sec'y of Health & Human Servs*., 991 F.2d 1570, 1575 (Fed. Cir. 1993).

When witness testimony is offered to overcome the presumption of accuracy afforded to contemporaneous medical records, such testimony must be "consistent, clear, cogent, and compelling." *Sanchez*, 2013 WL 1880825, at *3 (citing *Blutstein v. Sec'y of Health & Human Servs*., No. 90-2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)). In determining the accuracy and completeness of medical records, the Court of Federal Claims has listed four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe v. Sec'y of Health & Human Servs*., 110 Fed. Cl. 184, 203-04 (2013), *aff'd*, 746 F.3d 1334 (Fed. Cir. 2014). In making a determination regarding whether to afford greater weight to contemporaneous medical records or other evidence, such as testimony at hearing, there must be evidence that this decision was the result of a rational determination. *Burns*, 3 F.3d at 417.

C. Analysis of Expert Testimony

Establishing a sound and reliable medical theory often requires a petitioner to present expert testimony in support of his claim. *Lampe v. Sec'y of Health & Human Servs*., 219 F.3d 1357, 1361 (Fed. Cir. 2000). Vaccine Program expert testimony is usually evaluated according to the factors for analyzing scientific reliability set forth in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 594-96 (1993). *See Cedillo v. Sec'y of Health & Human Servs.*, 617 F.3d 1328, 1339

(Fed. Cir. 2010) (citing *Terran v. Sec'y of Health & Human Servs.*, 195 F.3d 1302, 1316 (Fed. Cir. 1999). "The *Daubert* factors for analyzing the reliability of testimony are: (1) whether a theory or technique can be (and has been) tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) whether there is a known or potential rate of error and whether there are standards for controlling the error; and (4) whether the theory or technique enjoys general acceptance within a relevant scientific community." *Terran*, 195 F.3d at 1316 n.2 (citing *Daubert*, 509 U.S. at 592-95).

The *Daubert* factors play a slightly different role in Vaccine Program cases than they do when applied in other federal judicial for a (such as the district courts). *Daubert* factors are usually employed by judges (in the performance of their evidentiary gatekeeper roles) to exclude evidence that is unreliable and/or could confuse a jury. In Vaccine Program cases, by contrast, these factors are used in the *weighing* of the reliability of scientific evidence proffered. *Davis v. Sec'y of Health & Human Servs*., 94 Fed. Cl. 53, 66-67 (2010) ("uniquely in this Circuit, the *Daubert* factors have been employed also as an acceptable evidentiary-gauging tool with respect to persuasiveness of expert testimony already admitted"). The flexible use of the *Daubert* factors to evaluate the persuasiveness and reliability of expert testimony has routinely been upheld. *See, e.g.*, *Snyder*, 88 Fed. Cl. at 742-45. In this matter (as in numerous other Vaccine Program cases), *Daubert* has not been employed at the threshold, to determine what evidence should be admitted, but instead to determine whether expert testimony offered is reliable and/or persuasive.

Respondent frequently offers one or more experts of her own in order to rebut a petitioner's case. Where both sides offer expert testimony, a special master's decision may be "based on the credibility of the experts and the relative persuasiveness of their competing theories." *Broekelschen v. Sec'y of Health & Human Servs*., 618 F.3d 1339, 1347 (Fed. Cir. 2010) (citing *Lampe*, 219 F.3d at 1362). However, nothing requires the acceptance of an expert's conclusion "connected to existing data only by the *ipse dixit* of the expert," especially if "there is simply too great an analytical gap between the data and the opinion proffered." *Snyder*, 88 Fed. Cl. at 743 (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 146 91997)); *see also Isaac v. Sec'y of Health & Human Servs*., No. 08-601V, 2012 WL 3609993, at *17 (Fed. Cl. Spec. Mstr. July 30, 2012), *mot. for review den'd*, 108 Fed. Cl. 743 (2013), *aff'd*, 540 Fed. App'x 999 (Fed. Cir. 2013) (citing *Cedillo*, 617 F.3d at 1339). Weighing the relative persuasiveness of competing expert testimony, based on a particular expert's credibility, is part of the overall reliability analysis to which special masters must subject expert testimony in Vaccine Program cases. *Moberly*, 592 F.3d at 1325-26 ("[a]ssessments as to the reliability of expert testimony often turn on credibility determinations"); *see also Porter v. Sec'y of Health & Human Servs*., 663 F.3d 1242, 1250 (Fed. Cir. 2011) ("this court has unambiguously explained that special masters are expected to consider the credibility of expert witnesses in evaluating petitions for compensation under the Vaccine Act").

D. Consideration of Medical Literature

Both parties filed medical and scientific literature in this case, but not all such items factor into the outcome of this decision. While I have reviewed all of the medical literature submitted in this case, I discuss only those articles that are most relevant to my determination and/or are central to Petitioner's case – just as I have not exhaustively discussed every individual medical record filed. *Moriarty v. Sec'y of Health & Human Servs.*, No. 2015-5072, 2016 WL 1358616, at *5 (Fed. Cir. Apr. 6, 2016) ("[w]e generally presume that a special master considered the relevant record evidence even though he does not explicitly reference such evidence in his decision") (citation omitted); *see also Paterek v. Sec'y of Health & Human Servs.,* 527 F. App'x 875, 884 (Fed. Cir. 2013) ("[f]inding certain information not relevant does not lead to – and likely undermines – the conclusion that it was not considered").

ANALYSIS

I. *Althen Prong One*

As described in detail above, a Program petitioner must show that the vaccine administered "can cause" the alleged injury by proposing a scientifically and medically reliable causation theory. Here, Dr. Latov offered his own opinion as to causation, bulwarked with literature suggesting that tetanus-containing vaccines like the Tdap vaccine Petitioner received have been associated with autoimmune diseases such as ADEM. He also presented two possible mechanisms —molecular mimicry and bystander activation – by which the vaccines could precipitate the autoimmune response. Tr. at 12.

Both of these theories have been accepted in other Program cases as reliable causal mechanisms for autoimmune-mediated demyelinating illnesses. *Raymo v. Sec'y of Health & Human Servs.,* No. 11-0654V , 2014 WL 1092274 (Fed. Cl. Spec. Mstr. Feb. 24, 2014) ("[a]lthough the precise biological mechanism has not been determined, molecular mimicry and bystander activation theories are biologically probable").

More specifically, the causal association between vaccines like Tdap and ADEM has been established in many prior Program cases. *See e.g., Kennedy v. Sec'y of Health & Human Servs.,* No. 09-474V, 2012 WL 1929801 (Fed. Cl. Spec. Mstr. May 8, 2012) (petitioner who received the meningococcal and Tdap vaccines and then developed ADEM was entitled to compensation based on the theory of molecular mimicry); *Lerwick v. Sec'y of Health & Human Servs.,* No. 06-847V, 2011 WL 4537874 (Fed. Cl. Spec. Mstr. Sept. 8, 2011) (ADEM and DTaP/Hep B vaccines); *Kuperus v. Sec'y of Health & Human Servs.,* No. 01-0060V, 2003 WL 22912885 (Fed. Cl. Spec. Mstr. Oct. 23, 2003) (awarded compensation in a DTaP/ADEM case based on the theory of

immune-mediated attack); *Johnson v. Sec'y of Health & Human Servs.,* No. 99-0219V, 2000 WL 1141582 (Fed. Cl. Spec. Mstr. July 27, 2000) (ADEM and Td vaccine).

As explained in such cases, components of the Tdap vaccine (inactivated diphtheria toxin or tetanus toxoid) have been associated with myelin destruction through an immune mediated attack. *Kuperus,* 2003 WL 22912885, at *9. This can occur when antigens in these components resemble a component of the myelin in the brain, ultimately triggering an immune response. *Id*. at *8. Dr. Latov's testimony and reports supported this idea, proposing molecular mimicry and bystander activation as mechanisms for the autoimmune reactions, and by citing studies recognizing vaccination as a preceding event to ADEM, allowing him to opine that the association was more than coincidental. Tr. at 12, Latov Supp. Rep at 4.

I find the theory similarly persuasive, and reliable from medical and scientific standpoint. Nor has Respondent adequately rebutted it.[10] Accordingly, Petitioner has met the first *Althen* prong.

II. *Althen Prong Two*

The primary challenge mounted by Respondent to the evidence offered for the second, "did cause" prong of the *Althen* test was his argument that ADEM was not the correct diagnosis (since if so, Petitioner's showing as to the first *Althen* prong regarding ADEM would be irrelevant). I find, however, that Petitioner has persuasively established that the record evidence best supports the ADEM diagnosis.

Consideration of the history of Petitioner's treatment best illustrates the propriety of her ADEM diagnosis. Although Mrs. Lozano's treaters initially included MS as part of the differential diagnosis (and did so properly in Dr. Latov's view, given the risks posed by MS), her subsequent clinical progression ultimately led them away from MS and toward ADEM. This was based on the resolution of Petitioner's lesions, as well as lab test results obtained closer in time to onset of her symptoms - the absence of oligoclonal bands in her CSF fluid, plus an elevated white blood cell count—all of which tended not to confirm an MS diagnosis. The fact that no treaters otherwise appear to have questioned ADEM since the winter of 2013 also suggests that the diagnosis is more likely than not correct.

[10] Respondent, via Dr. Leist, did offer evidence from the Institutes of Medicine ("IOM") positing that "mechanistic evidence regarding an association between diphtheria toxoid or acellular pertussis vaccine and ADEM is lacking." Leist Ex. Rep. at 8. I accept this evidence, and note that IOM evidence is generally given credence in the Program. *Garner v. Sec'y of Health & Human Servs.,* No. 15-063, 2017 WL 1713184 (Fed. Cl. Spec. Mstr. Mar. 24, 2017) Nevertheless, the overall showing by Petitioner was sufficient to meet her preponderant burden of proof.

Respondent was also unsuccessful in establishing that Mrs. Lozano had symptoms potentially related to her ADEM that began pre-vaccination. By and large, the medical record (and as interpreted by both experts) suggests that these potentially-neurologic symptoms that Petitioner might have experienced, such as a drooping face incident or difficulty opening a jar, are too anecdotal to deem significant, and instead appear to have been recounted by Petitioner and her family members at the time of her initial presentation to treaters in August 2012, in their reasonable effort to explain as exhaustively as possible any antecedent occurrences that might shed light on her then-alarming condition. Dr. Latov's explanation of the numbness Petitioner experienced prior to vaccination, in the last months of pregnancy as likely related to that pregnancy, was also more persuasive than Respondent's suggestion that it revealed a preexisting neurologic symptom. Tr. at 19. In addition, these pre-vaccination incidents were not supported by treatment records that would suggest a persistent neurological defect. Instead, the symptoms were only mentioned years after their original occurrence, with no support from contemporaneous medical records that indicate any relationship with her condition following vaccination. Overall, the record does not tie these anecdotal occurrences together in any manner sufficient to conclude that they reveal some preexisting neurologic problem.

Finally, Respondent's expert Dr. Leist proposed that Petitioner's proper diagnosis was instead PRES, attributable to her then-recent pregnancy. Although this argument had plausibility given the temporal relationship between Petitioner's pregnancy and subsequent neurologic symptoms, the overall record does not support it.[11] The strongest source for PRES as a possibility (besides the fact that Mrs. Lozano's symptoms post-dated her pregnancy) was the radiologist's inclusion of vasculitis (a broad category that would encompass PRES, among other things) in his write-up of Petitioner's first MRI performed in August 2012. But no subsequent treaters considered vasculitis as a possible explanation thereafter. Dr. Leist attempted to bulwark the reliability of the PRES diagnosis by identifying some clinical indicia supporting his preferred diagnosis, but Dr. Latov effectively and more persuasively ruled out PRES as a conclusion not as strongly supported by the medical record as ADEM.

[11] I am addressing Respondent's PRES argument within my *Althen* prong two discussion, since it relates directly to the accuracy of the ADEM diagnosis, and was in fact offered to contradict it. However, I would reach the same conclusion even if I more rigidly determined that Petitioner had carried her initial burden, and then considered (under the burden-shifting test applied) whether Respondent had carried his burden of establishing an alternative, unrelated cause for Mrs. Lozano's condition. *Heinzelman v. Sec'y of Health & Human Servs.*, No. 07-01V, 2008 WL 5479123, at *7 (Fed. Cl. Spec. Mstr. Dec. 11, 2008)("[o]nce…causation is established, the petitioner is entitled to compensation unless the government can show by a preponderance of the evidence that the injury is due to factors unrelated to the vaccine, i.e., an alternative cause").

Given the above, I conclude that Petitioner provided sufficient preponderant evidence to meet her *Althen* Two burden. She established a logical sequence of cause and effect from vaccine to injury that is supported by the evidentiary record.

III. *Althen Prong Three*

The third *Althen* prong also finds support in the record. As Petitioner and her expert established, an acceptable range of onset for an autoimmune condition is 2-42 days. Latov Ex. Rep. at 5. Other special masters have ruled in favor of Petitioners attempting to establish onset of ADEM after vaccination within the same range of time. *Kennedy,* 2012 WL 1929801, at *18 (Petitioner received the vaccine about two weeks prior to the onset of symptoms); *Kuperus,* 2003 WL 22912885, at *10 (finding that onset between ten and 21 days was appropriate). Here, Petitioner fell squarely within that range, since she experienced her first symptoms about 21 days after receiving the vaccine. Respondent did not establish that this timing was not medically acceptable or unreliable (and as noted above, also failed to establish that onset preceded vaccination). I therefore find that Petitioner has offered preponderant evidence in support of *Althen* prong three.

CONCLUSION

Petitioner has established her prima facie case by proving by a preponderance of the evidence for each of the *Althen* prongs, and is therefore entitled to compensation under the Vaccine Program.

In order to guide the parties through the damages phase of the action, a separate damages order will issue.

IT IS SO ORDERED.

s/Brian H. Corcoran
Brian H. Corcoran
Special Master